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Registration Decision RD2014-18

Indaziflam

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Registration Decision for Indaziflam

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Indaziflam Technical Herbicide (Registration Number 30219) and Esplanade SC Herbicide, containing the technical grade active ingredient indaziflam, to control or suppress annual grasses and broadleaf weeds in non-residential non-crop areas such as: railroad and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, and municipal and government sites.

Indaziflam Technical Herbicide is fully registered in Canada to control both grassy and broadleaf weeds in pome fruit, stone fruit, tree nuts and grapes. The detailed review for Indaziflam Technical Herbicide can be found in the Proposed Regulatory Decision PRD2011-20, *Indaziflam* and the Registration Decision RD2012-08, *Indaziflam*

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2014-04, *Indaziflam*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for indaziflam and summarizes the Agency's decision, the reasons for it. The PMRA received no third party comments on PRD2014-14. This decision is consistent with the proposed registration decision stated in PRD2014-04.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2014-04, *Indaziflam* that contains a detailed evaluation of the information submitted in support of this registration.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Indaziflam?

Indaziflam belongs to the chemical class of alkylazines and acts in susceptible plants by inhibiting the synthesis of cellulose and cell wall biosynthesis. Indaziflam acts only where cellulose synthesis is occurring such as in actively growing meristematic tissues, dividing cells, expanding cells, and growing roots. Indaziflam has little to no impact on fully developed leaves, tissues, and plant organs since cell wall formation has already been completed.

Indaziflam is classified as a Group 29 Herbicide by the Weed Science Society of America and as a Group L Herbicide (inhibition of cellulose synthesis) by the Herbicide Resistance Action Committee.

Indaziflam is the active ingredient of Esplanade SC Herbicide, which is intended for residual control or suppression of grasses and broadleaf weeds in non-residential, non-crop areas. Esplanade SC Herbicide is determined to be agronomically similar to Indaziflam 200 SC Herbicide (Registration Number 30221), which is registered for pre-emergent residual control or suppression of grasses and broadleaf weeds in pome fruits, stone fruits, grapes, and tree nuts in Eastern Canada and British Columbia.

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3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

Health Considerations

Can Approved Uses of Indaziflam Affect Human Health?

Indaziflam is unlikely to affect your health when used according to label directions.

Potential exposure to indaziflam may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, indaziflam was of low acute oral, dermal and inhalation toxicity. Indaziflam was minimally irritating to the eyes and non-irritating to the skin, and did not cause an allergic skin reaction.

Esplanade SC Herbicide was considered to have a similar toxicity profile to Indaziflam 500 SC Herbicide. The acute toxicity of the end-use product Indaziflam 500 SC Herbicide containing indaziflam was low via the oral, dermal and inhalation routes of exposure. It was non-irritating to the eyes and skin and did not cause an allergic skin reaction.

Indaziflam did not cause cancer in animals and did not damage genetic material. There was no indication that indaziflam caused damage to the immune system. Indaziflam did not cause birth defects in animals. Health effects in animals given repeated doses of indaziflam included effects on body weight, and the liver, kidney, thyroid, nervous and reproductive systems with neurotoxicity being the primary effect.

When indaziflam was given to pregnant or nursing animals, there were effects on the developing fetus and juvenile animal. In rat reproductive toxicity studies, effects consisted of decreased body weights, decreased spleen, uterine and brain weights, decreased litter sizes, delayed sexual maturation, neurological effects, and diarrhea. In the rabbit developmental toxicity study, effects consisted of decreased body weights and increased skeletal variations. The effects were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to indaziflam than the adult animal.

The risk assessment protects against the effects of indaziflam by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Occupational Risks From Handling Esplanade SC Herbicide

Occupational risks are not of concern when Esplanade SC Herbicide is used according to the label directions, which include protective measures.

Workers and custom applicators who mix, load or apply Esplanade SC Herbicide as well as field workers entering freshly treated areas can come in direct contact with Esplanade SC Herbicide residues on the skin. Therefore, the label specifies that anyone mixing/loading and applying Esplanade SC Herbicide must wear a long-sleeved shirt, long pants and chemical-resistant gloves. The label also requires that workers do not enter treated fields after application until residues have dried. Taking into consideration these label statements, the number of applications and the expectation of the exposure period for handlers and workers, the occupational risk to these individuals is not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Indaziflam Is Introduced Into the Environment?

Indaziflam enters the environment when it is used to control weeds in non-residential non-crop areas.

Indaziflam may pose a risk to terrestrial and aquatic plants.

In water, indaziflam does not readily break down, and will move from the water to the sediment where it is persistent. Indaziflam does not remain in soil for long periods of time because soil bacteria break it down. Depending on the soil type, 50% of the applied indaziflam has been shown to break down within a time period ranging from less than one month up to approximately three months. This breakdown of indaziflam results in the formation of three breakdown products. Two of these products will not remain in the soil as they are readily broken down by microbes in the soil. The third product may persist for extended periods of time; however, this is highly dependent on the soil type. The movement of indaziflam and its breakdown products in the environment is expected to be minimal. Available information suggests that indaziflam is not expected to be found in air and not expected to move through the soil into groundwater. This was confirmed with modelling which resulted in low predicted levels of indaziflam and its breakdown products in groundwater.

Indaziflam does not present a risk to wild mammals, birds, bees, invertebrates, freshwater or marine invertebrates and fish, or amphibians. Exposure to indaziflam can affect terrestrial and aquatic plants. To protect terrestrial and aquatic plants from spray drift, spray buffer zones of 15 metres and 1 metre are required for terrestrial and aquatic habitats,[5] respectively. To protect aquatic plants from the potential effects of runoff, a label statement to minimize runoff will be required, as well as hazard based label statements for toxicity to terrestrial and aquatic plants.

Value Considerations

What Is the Value of Esplanade SC Herbicide?

Esplanade SC Herbicide, as a pre-emergent treatment in non-residential non-crop areas, provides residual control or suppression of grasses and broadleaf weeds.

A single application of Esplanade SC Herbicide at the rate of 75 g a.i./ha provides effective residual control or suppression of grasses, including barnyard grass, giant foxtail, green foxtail, Italian ryegrass, large crabgrass, wild proso millet, yellow foxtail, wild barley, wild oats, brome grasses, medusa head, bluestem broomsedge, and volunteer common rye, and broadleaf weeds, including annual sow-thistle, black mustard, common groundsel, field bindweed, lamb's-quarters, prickly lettuce, redroot pigweed, shepherd's purse, spotted spurge, stork's-bill, white sweet clover, wild mustard, yellow starthistle, kochia, St. John's wort, cudweed, dog fennel, smooth hawk's-beard, and morning glory in non-residential non-crop areas such as: railroads and rail yards, managed roadsides, fence rows, utilities, hardscapes, industrial, military bases, municipal and government sites.

Esplanade SC Herbicide provides an additional option for herbicide mode of action rotation for residual control or suppression of both grassy and broadleaf weeds in non-residential non-crop areas. Esplanade SC Herbicide may also be applied in tank mixes with other herbicides for additional residual weed control and/or burndown control of emerged weeds. The application of Esplanade SC Herbicide does not restrict the sequential use of other chemicals of alternate modes of action.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Esplanade SC Herbicide to address the potential risks identified in this assessment are as follows.

[5] Some areas do not require buffer zones for terrestrial plants (railways, rights-of-ways, etc.)

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with indaziflam on the skin or through inhalation of spray mists, anyone mixing, loading and applying Esplanade SC Herbicide must wear a long-sleeved shirt, long pants and chemical-resistant gloves while mixing/loading, applying and during clean-up and repair. In addition, standard label statements to protect against drift during application are present on the label. Entry into treated areas is not permitted until sprays have dried to protect workers following application.

Environment

Spray buffer zones of 1 and 15 meters are required to protect aquatic and terrestrial plants, respectively.

Hazard based label statements for toxicity will be required for terrestrial plants and aquatic plants.

Run-off statements will be required on the label.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2014-04, *Indaziflam)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[6] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[6] As per subsection 35(1) of the *Pest Control Products Act.*